

REMARKS

Favorable reconsideration and withdrawal of the objections and rejections set forth in the above-mentioned Official Action in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 1-11, and 25-27 were elected with traverse following the notice of restriction. Claim 27 is being canceled, and thus claims 1-11, and 25-26 are now pending in the application.

Claims 1-11, 25-26 have been amended. Claims 28-47 are newly presented. A new title is voluntarily submitted as more descriptive of the claimed invention. It is respectfully submitted that no new matter has been added. Claims 11, 25, and 29 are independent claims.

Claim 11 is amended and refers to an IRF (immuno-responsiveness factor relating to cytoprotective agents), and an NED (non-endocrine disrupting value relating to the use of no known endocrine disrupting agents) as supported in the original specification initially on pages 4 and 5, paragraph [11] lines 1-9 and again on page 5, paragraph [12], lines 1-7, then again on page 13, paragraph [0053], lines 2-7, page 16, paragraph [0063], lines 11 and 12, and also on page 17, paragraph [0067], lines 5-9. SPF (sun protection factor) is a well known criteria for

those "skilled in the art" regarding products for sun protection.

Claim 25 is amended and refers to a method of making the UV protective non-endocrine disrupting composition, such a method finding broad support on page 18, paragraph [0075], lines 1-5 of the original specification.

Claim 29, is newly added and refers to at least one organic, non-endocrine disrupting sunscreen agent. This claim is fully supported in the original specification on page 14, paragraph [0059], line 3, indicating that butyl-methoxydibenzoylmethane has been shown as a non-endocrine disrupter (as also presented in the study by Schlumph, et. al., the reference of which is supplied as an addendum to this response).

Claims 26 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. An amendment is made to claim 26 and cancellation of claim 27 to resolve the issue, as claim 26 is no longer a multiple dependent claim.

Claim 25 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 15 of prior U.S. Patent No. 5,980,871, being a double patenting rejection. Claim 25 has

since been amended to include the limitation of non-endocrine disruptive composition. Following this amendment, it is respectfully submitted that said composition in claim 25 is patentably distinguishable over U.S. Patent No. 5,980,871. In view of the foregoing, it is respectfully submitted that independent claim 25 is neither anticipated, described, shown, nor suggested by U.S. Patent No. 5,980,871.

Claim 1, and those dependent thereon, are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner recited the limitation of "non-endocrine disrupting agent" in asserting that there is no guidance as to how to select sunscreens that are "non-endocrine disrupting." A non-endocrine disrupting invention is within itself, a novel embodiment of the present invention, ie. prior to this invention, such sunscreens or sun-blocks did not exist anywhere. This rejection is respectfully traversed.

Independent claim 1, and dependent claims 2-11, and 26 have been amended to enable one skilled in the art to make and use the invention as described in the specification. The limitation of non-endocrine disrupting agents in said sun-block are restrictive in nature, and are supported in the specification beginning on page 5, paragraph [0013], line 7. Such compounds

listed are those that are known endocrine disrupting agents, and thus must be avoided when making the sun-block compound of the present invention. A reference list is included in the Information Disclosure Statement Sheet that cites the website for the Environmental Protection Agency, that lists some endocrine disrupting agents.

Additionally, during an in-office interview with the examiner on July 17, 2002, the applicant showed the examiner where such support for the claims was located in the specification, and the examiner stated that the EPA specific website should be included in the IDS. The applicant also made mention of, and the examiner requested copies of: "Spotlight On Sunscreens" MARC S. REISCH, C & EN, Dec 3, 2001; and the website www.lineone.net be included in this response. Copies of these references are included for the examiner's convenience in this response. It is therefore, respectfully submitted that claims 1-11, and 26 as amended, are fully supported as written in the original specification in such a way as to enable one skilled in the art to make and use the present invention.

The Examiner again rejects claims 1-11, 26 and 27 under 35 U.S.C. § 112, as being indefinite for failing to particularly point out and distinctly claim the invention. Amendment of these claims include the removal of the terms "such as," "about," and "preferably," and inclusion of the required limitation of only non-endocrine disrupting agents. Claim 4 has since been amended

to remove the Markush language to make said claim more definite. Claims 5 and 6 have also been amended to provide proper antecedent basis. Claims 5-11 have been amended to provide antecedent basis for a sun-block composition. It is respectfully submitted that claims 1-11, and 26 as amended particularly point out and distinctly claim the invention. Claim 27 has since been canceled.

Claims 1, 4-10 and 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lukenbach et al. (US 5,980,871). Again, independent claims 1 and 25 have been amended to include the limitation of non-endocrine disrupting agents, and claim 27 has since been canceled. This rejection is respectfully traversed.

Independent claim 1, as amended, calls for a sun-block composition comprising at least one inorganic, non-endocrine disrupting sun-blocking agent; at least one non-endocrine disrupting emollient or mixtures thereof; and optionally; an oil component, said composition capable of protecting skin from harmful effects of radiation including sunlight and ultraviolet light.

Independent claim 25 as amended calls for a method of making a UV-protective, non-endocrine disruptive composition comprising; adding and mixing de-ionized water, cold pressed aloe, and zinc oxide or titanium dioxide or both in combination

to a vessel; then, adding an oil component; then, mixing said composition in said vessel.

Luckenbach contains no limitations regarding non-endocrine disrupting agents, nor does the reference make mention of the existence of endocrine substances and therefore is not the same invention. In view of the foregoing, it is respectfully submitted that independent claim 1, and those dependent upon claim 1, are neither anticipated, described, shown, nor suggested by Luckenbach.

Luckenbach also makes no mention of any method of making a non-endocrine disruptive composition. Luckenbach discloses a method for making a sunscreen composition with steps including heating the water, adding an anionic emulsifier, and adjusting the pH of said composition to above 5, all of which are not included in the amended claim 25 of the present invention. In view of the foregoing, it is respectfully submitted that independent claim 25 is neither anticipated, described, shown, nor suggested by Luckenbach.

Claims 1-6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wenker (US 5,972,362) in view of Strickland et al. (US 5,824,659). Again, independent claim 1 has been amended to include the limitation of non-endocrine disrupting agents. This rejection is respectfully traversed.

Wenker calls for 17-19% Aloe Vera gel, which is not the cold pressed aloe of the present invention, and in view of

Strickland, does not make use of cold pressed aloe barbadensis Miller, and in addition, neither patent specifically calls for a restriction in the use of non-endocrine disrupting agents only. Wenker calls for the use of glycerin, which if petroleum based is a suspected endocrine disrupter, and the use of a tincture of iodine, which is not called for in the present invention. Wenker also calls for "other conventional ingredients," which is vague and indefinite to those skilled in the art. Additionally, during an in-office interview with the examiner on July 17, 2002, the applicant showed the examiner, and supplied her with samples indicating the novelty of the applicant's invention by incorporation of the use of cold pressed aloe, only non-endocrine disrupting agents, and the optional use of vegetable glycerin. Neither Wenker nor Strickland individually or combined suggest or motivate the exclusive use of non-endocrine disrupting agents and thus in view of the foregoing, it is respectfully submitted that independent claim 1 and dependent claims 2-6 are neither anticipated, described, shown, nor suggested by Wenker or Strickland or the combination of the references.

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lukenbach et al. in view of Strickland et al. Since claims 2 and 3 have since been amended and remain based on now amended claim 1, this rejection is respectfully traversed.

Amended dependent claims 2 and 3 are now limited to a sun-block composition, as in claim 1, wherein said sun-block composition comprises non-endocrine disrupting sun-block agents only. Where one of ordinary skill may have been motivated to employ aloe extract of Strickland et al. in sunscreen compositions of Lukenbach et al., neither refers to the exclusive use of non-endocrine disrupting agents for sunscreens or sun-blocks, as is a required embodiment of the present invention.

In view of the foregoing, it is respectfully submitted that dependent claims 2 and 3 are neither anticipated, described, shown, nor obvious in light of Lukenbach et al. in view of Strickland et al.

The Examiner states that it is the applicants' burden to show novel and unobvious differences between the claimed product and the prior art, in light of the fact that the reference is silent with respect to IRF and NED compositions, and that the Office does not have the facilities for examining and comparing applicants' product with the prior art. Thus, claim 11 is rejected under 35 U.S.C. § 103(a) as anticipated or obvious over Lukenbach et al. MPEP § 706.02(j) states that the initial burden is on the examiner to "provide some suggestion of the desirability of doing what the inventor has done". In this case, no suggestion is expressly or impliedly made in the prior art references of Lukenbach, et. al. as to the use of strictly

non-endocrine disrupting agents for sun-block and/or sunscreen substances. In addition, MPEP § 2112 provides that in relying upon the theory of inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art". The present invention, with the newly amended claims is restricted to the use of non-endocrine disrupting agents only. Again, no mention is made in the prior art references cited by the examiner of non-endocrine disrupting agents. In addition, there is an absence of a suitably operative process for making this composition of matter and in view of the foregoing, it is respectfully submitted that dependent claim 11 is neither anticipated, described, shown, nor obvious in light of Lukenbach et al.

Claims 9-11 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Wenker. Again, dependent claims 9-11 have been amended and this rejection is respectfully traversed.

As was stated above, the Examiner states that it is the applicants' burden to show novel and unobvious differences between the claimed product and the prior art, in light of the fact that the reference is silent with respect to pH, SPF, IRF, and NED of the composition. Again, as cited under MPEP §§

706.02(j) and 2112, the questionable characteristics of the present invention are significantly different in view of the amendments to the claims in question. Wenker makes no mention of non-endocrine disrupters or of immuno-enhancing agents of the present invention and the values given for pH, SPF, IRF, and NED of the present invention must be assumed to be true and valid. The sample compositions presented to the examiner on July 17 also complied with these pH, SPF, IRF, and NED values. In addition, based on recent scientific data from articles by Schlumpf and others in reputable, peer reviewed scientific journals (as supplied in the addendum to this response and in the IDS) there is reasonable evidence that supports the claimed IRF and NED values characterize the therapeutic quality based on a reasonable correlation between the activity in question (i.e. no endocrine disrupters present and the enhanced cytoprotective nature of the exclusive use of cold pressed aloe in the present composition - all of which is unknown in the prior art) and the asserted utility (a more beneficial composition for mammalian skin protection from UV and sunlight). Applicant respectfully submits that; he does not have to prove that a correlation exists between a particular activity and asserted therapeutic use of a compound or provide actual evidence of success in treating humans where such a utility is asserted. In view of the foregoing, it is respectfully submitted that dependent claim 11 is neither anticipated, described, shown, nor obvious in

light of Wenker and that the claim 11 of the present invention is patentable over the prior art.

Favorable reconsideration and early passage to issue of the present application are now earnestly solicited.

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Please amend Claims 1-11, and 25-26 to the present version with markings to show changes made:

1. (Amended) A sun-block composition comprising:

(a) at least one inorganic, non-endocrine disrupting sun-blocking agent;

(b) [optionally at least one non-endocrine disrupting sunscreen agent;] at least one non-endocrine disrupting emollient or mixtures thereof; and optionally;

(c) [at least one non-endocrine disrupting emollient or mixtures thereof;] an oil component,

[(d)and; (e)an optional oil component comprising a carrier oil, preferably an essential oil of a naturally occurring substance;]

said composition capable of protecting skin from harmful effects of radiation including [ultraviolet light or sunlight] sunlight and ultraviolet light.

2. (Amended) A sun-block composition according to claims 1, wherein said emollient is aloe barbadensis Miller.

3. (Amended) A sun-block composition according to claim 2, wherein said emollient includes oligosaccharides of aloe barbadensis Miller that inhibit loss of skin immunocompetency.

4. (Amended) A sun-block composition according to claim 1, wherein said sun-blocking agents, emollients, and carrier or essential oils or both include other non-endocrine disruptive agents [consisting of] comprising a sunless tanning agent, an anti-microbial agent, a de-pigmentation agent, [and] an anti-aging agent, an anti-fungal agent, and an insect repellent [and] or any combination thereof, and wherein one or more of said agents [may be] are topically active.

5. (Amended) A [sunscreen] sun-block composition according to claim 1, wherein said inorganic [sunscreen] sun-block agent is titanium dioxide, zinc oxide, silica or silicon dioxide, or mixtures thereof.

6. (Amended) A [sunscreen] sun-block composition according to claim 5, wherein said inorganic [sunscreen] sun-block agent is [titanium dioxide] zinc oxide.

7. (Amended) A [sunscreen] sun-block composition according to claim 6, wherein said [titanium dioxide] zinc oxide has a primary particle size of less than [about] 30 nm.

8. (Amended) A [sunscreen] sun-block composition according to claim 1, wherein said emollient is a salt of a fatty acid, where said salt of said fatty acid has been determined to be non-endocrine disrupting.

9. (Amended) A [sunscreen] sun-block composition according to claim 1, wherein said composition has a pH of at least of 5.

10. (Amended) A [sunscreen] sun-block composition according to claim 9, wherein said pH is from [about] approximately 6.5 to [about] approximately 8.5.

11. (Amended) A [sunscreen] sun-block composition according to claim 1, having a Sun Protection Factor (SPF) of at least 10, and an immuno-responsiveness factor (IRF) of greater than zero, and a non-endocrine disrupter (NED) factor not greater than zero.

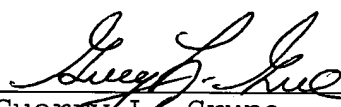
25. (Amended) A method of making a UV-protective, non-endocrine disruptive composition comprising;

- (a) adding de-ionized water, cold pressed aloe, and zinc oxide or titanium dioxide or both in combination to a vessel;
- (b) then [heating the water], adding an oil component;

(c) then, [adding a carrier oil and an emollient to said vessel] mixing said composition in said vessel.

26. (Amended) [A UV-protective] The sun-block composition of [claims] claim 1 [,4, 12,23,24, and 25 containing about], wherein said composition contains greater or equal to 2% [to about 25%] of an inorganic sun-block [or sunscreen] agent, [from about] greater than or equal to 0.5% [to about 10%] of an emollient, and [from about] greater than or equal to 0.5% [to about 10%] of an oil component comprising a carrier oil, [preferably an essential oil from natural occurring substances] where said carrier oil is a desirable essential oil derived from earth grown substances.

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